



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: **Jon Wolff *et al.***)
)
Serial No.: **10/083,456**)
)
Filed: **February 26, 2002**)
)
Group Art Unit:)

For: **COMPOSITIONS AND METHODS FOR DRUG DELIVERY USING pH SENSITIVE MOLECULES**

INFORMATIONAL STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. 1.56, applicant hereby calls to the attention of the Patent and Trademark Office the publications listed on the attached PTO 1449. One copy of each publication is attached.

UNITED STATES PATENTS

<u>Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
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FOREIGN PATENTS

<u>Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
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REFERENCES CITED

Adami et al., "metabolic stability of glutaraldehyde cross-linked peptide DNA condensates," Journal of Pharmaceutical Sciences; Aug. 1999, vol. 88, no. 8, pp. 739-745

Berton et al., "Uptake of oligonucleotide-loaded nanoparticles in prostatic cancer cells and their intracellular localization," European Journal of Pharmaceutics and Biopharmaceutics; 1999, vol. 47, pp. 119-123

Birch "reduction by dissolving metals," 1946, vol. 3, pp. 593-597

Blattler et al., "New heterobifunctional protein cross-linking reagent that forms an acid-labile link," Biochemistry; 1985, vol. 24, pp. 1517-1524

Blessing et al., "Template oligomerization of DNA-bound cations produces calibrated nanometric particles," *J. Am. Chem. Soc.*; 1998, vol. 120, pp. 8519-8520

Boussif et al., "A versatile vector for gene and oligonucleotide transfer into cells in culture and in vivo: polyethylenimine," *Proc. Natl. Acad. Sci.*; Aug. 1995, vol. 92, pp. 7297-7301

Budker et al., "The efficient expression of intravascularly delivered DNA in rat muscle," *Gene Therapy*; 1995, vol. 5, pp. 272-276

Curiel et al., "adenovirus enhancement of transferring-polylysine-mediated gene delivery," *Proc. Natl. Acad. Sci.*; Oct. 1991, vol. 88, pp. 8850-8854

Danko et al., "high expression of naked plasmid DNA in muscles of young rodents," *Human Molecular Genetics*; 1997, vol. 6, no. 9, pp. 1435-1443

Duzgunes et al., "pH-sensitive liposomes," *California Biotechnology*; pp.113-131

Felgner et al., "Lipofection: a highly efficient, lipid-mediated dna-transfection procedure," *Proc. Natl. Acad. Sci. Usa*; nov. 1987, vol. 84, pp. 7413-7417

Gerweck et al., "Cellular pH gradient in tumor versus normal tissue: potential exploitation for the treatment of cancer," *Cancer Research*; march 15, 1996, vol. 56, pp. 1194-1198

Gill et al., "Calculation of protein extinction coefficients from amino acid sequence data," *Analytical Biochemistry*; 1989, vol. 182, pp. 319-326

Goula et al., "size, diffusibility and transfection performance of linear PEI/DNA complexes in the mouse central nervous system," *Gene Therapy*; 1998, vol. 5, pp. 712-717

Hawley-Nelson et al., "Lipofectamine reagent: a new, higher efficiency polycationic liposome transfection reagent," *Focus*; vol. 15, no. 3, pp. 73-79

Hu et al., "Characterization of norfloxacin release from tablet coated with a new pH-sensitive polymer, p-4135f," *Journal of Drug Targeting*; 1999, vol. 7, no. 3, pp. 223-232

Jain et al., "Controlled drug delivery by biodegradable polyester devices: different preparative approaches," *Drug Development and Industrial Pharmacy*; 1998, vol. 24, no. 8, pp. 703-727

Kamata et al., "Amphiphilic peptides enhance the efficiency of liposome-mediated DNA transfection," *Nucleic Acids Research*; 1994, vol. 22, no. 3, pp. 536-537

Kichler et al., "Efficient gene delivery with neutral complexes of lipospermine and thiol-reactive phospholipids," *Biochemical and Biophysical Research Communications*; 1995, vol. 209, no. 2, pp. 444-450

Kirby, "Effective Molarities for intramolecular reactions," *University Chemical Laboratory, Cambridge, England*; pp. 187-278

Kishore et al., "Polymers containing disulfide, tetrasulfide, diselenide and ditelluride linkages in the main chain," *Advances in Polymer Sciences*; 1995, vol. 121

Kresge et al., "vinyl ether hydrolysis. 9. isotope effects on proton transfer from the hydronium ion," *Journal of the American Chemical Society*; Oct. 1977, vol. 99, no. 22, pp. 7228-7233

Legendre et al., "Delivery of Plasmid DNA into mammalian Cell Lines using ph-sensitive liposomes: comparison with cationic liposomes," *Pharmaceutical Research*; 1992, vol. 9, no. 10, pp. 1235-1241

Lowman et al., "Oral delivery of insulin using pH-responsive complexation gels," *Journal of Pharmaceutical Science*; sep. 1999, vol. 88, no. 9, pp. 933-937

Madsen et al., "Complexation graft copolymer networks: swelling properties, calcium binding and proteolytic enzyme inhibition," *Biomaterials*; 1999, vol. 20, pp. 1701-1708

Mechtler et al., "Gene transfer mediated by influenza virus peptides: the role of peptide sequences," *New Journal of Chemistry*; 1997, vol. 21, pp. 105-111

Metrikin et al., "Intravitreal drug administration with depot devices," *Current Opinion in Ophthalmology*; 1994, vol. 5, pp. 21-29

Meyer et al., "Copolymers of N-isopropylacrylamide can trigger pH sensitivity to stable liposomes," *FEBS Letters*; 1998, vol. 421, pp. 61-64

Murthy et al., "the design and synthesis of polymers for eukaryotic membrane disruption," *Journal of Controlled Release*; 1999, vol. 61, pp. 137-143

Nishikubo et al., "Degradation of dehydrochlorinated ly(epichlorohydrin) using photo-generated cationic catalysts," *Polymer Science: Part A: Polymer Chemistry*; 1986, vol. 24, pp. 1097-1108

O'Brien-Simpson et al., "Polymerization of Unprotected Synthetic Peptides: A View toward Synthetic Peptide Vaccines," *J. Am. Chem. Soc.*; 1997, vol. 119, pp. 1183-1188

Ohmori et al., "The Enhancing effect of anionic α -Helical peptide on cationic peptide-mediating transfection systems," *Biochemical and Biophysical Research Communications*; 1997, vol. 235, pp. 726-729

Pastan et al., "Pseudomonas exotoxin: chimeric toxins" *The Journal of Biological Chemistry*; Sept. 15 1989, vol. 264, no. 26, pp. 15157-15160

Perez et al., "Comonomer sequence assignment of the Cn.m.r. spectra of some poly(epichlorohydrin) derivatives obtained by nucleophilic substitution," *Polymer*; 1998, vol. 39, no. 17, pp. 3885-3892

Remy et al., "Gene Transfer with a series of lipophilic DNA-binding molecules," *Bioconjugate Chem.*; 1994, vol. 5, pp. 647-654

Remy et al., "Targeted gene transfer into hepatoma cells with lipopolyamine-condensed DNA particles presenting galactose ligands: a stage toward artificial viruses," *Proc. Natl. Acad. Sci.*; Feb. 1995, vol. 92, pp. 1744-1748

Seetharam et al., "Increased cytotoxic activity of pseudomonas exotoxin and two chimeric toxins ending in kdel," *The Journal of Biological Chemistry*; Sept. 15 1991, vol. 266, no. 26, pp. 17376-17381

Senior et al., "Interaction of positively-charged liposomes with blood: implications for their application in vivo," *Biochimica et Biophysica Acta*; 1991, vol. 1070, pp. 173-179

Seymour et al., "Polymer Chemistry" polymer chemistry;

Sezaki et al., "soluble macromolecular carriers for the delivery of antitumor drugs," Elsevier Science Publishers; 1989 pp. 247-266

Thorpe et al., "Comparison of two anti-thy 1.1-abrin a-chain immunotoxins prepared with different cross-linking agents: antitumor effects, in vivo fate, and tumor cell mutants," *JNCI*; nov. 1987, vol. 79, no. 5, pp. 1101-1111

Trubetskoy et al., "Caged DNA does not aggregate in high ionic strength solutions," *Bioconjugate Chem.*; 1999, vol. 10, pp. 624-628

Trubetskoy et al., "Layer-by-layer deposition of oppositely charged polyelectrolytes on the surface of condensed DNA particles," *Nucleic Acids Research*; 1999, vol. 27, no. 15, pp. 3090-3095

Trubetskoy et al., "Quantitative Assessment of DNA Condensation," *Analytical Biochemistry*; 1999, vol. 267, pp. 1-5

Trubetskoy et al., "Self-assembly of DNA-polymer complexes using template polymerization," *Nucleic Acids Research*; 1998, vol. 26, no. 18, pp. 4178-4185

Wagner et al., "Delivery of drugs, proteins and genes into cells using transferrin as a ligand for receptor-mediated endocytosis," *Advanced Drug Delivery Reviews*; 1994, vol. 14, pp. 113-135

Wagner et al., "Influenza virus hemagglutinin ha-2 n-terminal fusogenic peptides augment gene transfer by transferring-polylysine-DNA complexes: toward a synthetic virus-like gene-transfer vehicle," *Proc. Natl. Acad. Sci.*; Sept. 1992, vol. 89, pp. 7934-7938

Wetters et al., "Copolymers of 2-(dimethylamino)ethyl methacrylate with ethoxytriethylene glycol methacrylate or n-vinyl-pyrrolidone as gene transfer agents," *Journal of Controlled Release*; 2000, vol. 64, pp. 193-203

Wolfert et al., "Characterization of vectors for gene therapy formed by self-assembly of DNA with synthetic block co-polymers," *Human Gene Therapy*; Nov. 1996, vol. 7, pp. 2123-2133

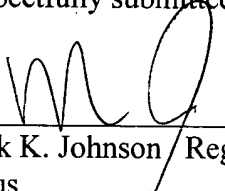
Wolff et al., "Direct gene transfer into mouse muscle in vivo," Science; 1990, vol. 247, pp. 1465-1468

Zauner et al., "Rhinovirus-mediated endosomal release of transfection complexes," Journal of Virology; feb. 1995, vol. 69, no. 2, pp. 1085-1092

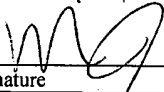
Zhou et al., "DNA transfection mediated by cationic liposomes containing lipopolylysine: characterization and mechanism of action," Biochimica et Biophysics Acta; 1994, vol. 1189, pp. 195-203

Zhou et al., "Lipophilic polylysines mediate efficient DNA transfection in mammalian cells," Biochimica et Biophysics Acta; 1991, vol. 1065, pp. 8-14

Respectfully submitted,



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<p>I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on <u>8/4/03</u>.</p> <p> _____ Signature</p>



INFORMATION DISCLOSURE STATEMENT BY APPLICANT FORM PTO-1449	Attorney Docket No.: 16.06	Serial No.: 10/083,456
	Applicant: Jon Wolff et al.	Group: Examiner:

U.S. PATENT DOCUMENTS

Exmnr Intl	Seq	Patent Number	Issue Date	Patentee	Class	Sub Class	Filing Date
							February 26, 2002

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

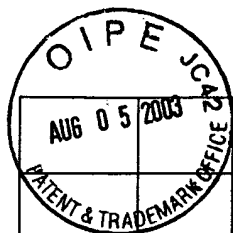
		Document Number	Publ. Date	Country or Patent Office	Class	Sub Class	Transl. Yes No	

OTHER DOCUMENTS (Including Author, Title, Date Pertinent Pages, etc.)

	Metrikin et al., "Intravitreal drug administration with depot devices," Current Opinion in Ophthalmology; 1994, vol. 5, pp. 21-29
	Duzgunes et al., "pH-sensitive liposomes," California Biotechnology; pp.113-131
	Hu et al., "Characterization of norfloxacin release from tablet coated with a new pH-sensitive polymer, p-4135f," Journal of Drug Targeting; 1999, vol. 7, no. 3, pp. 223-232
	Hawley-Nelson et al., "Lipofectamine reagent: a new, higher efficiency polycationic liposome transfection reagent," Focus; vol. 15, no. 3, pp. 73-79
	Kirby, "Effective Molarities for intramolecular reactions," University Chemical Laboratory, Cambridge, England; pp. 187-278
	Legendre et al., "Delivery of Plasmid DNA into mammalian Cell Lines using pH-sensitive liposomes: comparison with cationic liposomes," Pharmaceutical Research; 1992, vol. 9, no. 10, pp. 1235-1241
	Sezaki et al., "soluble macromolecular carriers for the delivery of antitumour drugs," Elsevier Science Publishers; 1989pp. 247-266
	Jain et al., "Controlled drug delivery by biodegradable poly(ester) devices: different preparative approaches," Drug Development and Industrial Pharmacy; 1998, vol. 24, no. 8, pp. 703-727
	Berton et al., "Uptake of oligonucleotide-loaded nanoparticles in prostatic cancer cells and their intracellular localization," European Journal of Pharmaceutics and Biopharmaceutics;



	1999, vol. 47, pp. 119-123
	Gerweck et al., "Cellular pH gradient in tumor versus normal tissue: potential exploitation for the treatment of cancer," <i>Cancer Research</i> ; march 15, 1996, vol. 56, pp. 1194-1198
	Thorpe et al., "Comparison of two anti-thy 1.1-abrin a-chain immunotoxins prepared with different cross-linking agents: antitumor effects, in vivo fate, and tumor cell mutants," <i>JNCI</i> ; nov. 1987, vol. 79, no. 5, pp. 1101-1111
	Gill et al., "Calculation of protein extinction coefficients from amino acid sequence data," <i>Analytical Biochemistry</i> ; 1989, vol. 182, pp. 319-326
	Felgner et al., "Lipofection: a highly efficient, lipid-mediated dna-transfection procedure," <i>Proc. Natl. Acad. Sci. Usa</i> ; nov. 1987, vol. 84, pp. 7413-7417
	Lowman et al., "Oral delivery of insulin using pH-responsive complexation gels," <i>Journal of Pharmaceutical Science</i> ; sep. 1999, vol. 88, no. 9, pp. 933-937
	Ohmori et al., "The Enhancing effect of anionic α -Helical peptide on cationic peptide-mediating transfection systems," <i>Biochemical and Biophysical Research Communications</i> ; 1997, vol. 235, pp. 726-729
	Madsen et al., "Complexation graft copolymer networks: swelling properties, calcium binding and proteolytic enzyme inhibition," <i>Biomaterials</i> ; 1999, vol. 20, pp. 1701-1708
	Zauner et al., "Rhinovirus-mediated endosomal release of transfection complexes," <i>Journal of Virology</i> ; feb. 1995, vol. 69, no. 2, pp. 1085-1092
	Zhou et al., "DNA transfection mediated by cationic liposomes containing lipopolylysine: characterization and mechanism of action," <i>Biochimica et Biophysics Acta</i> ; 1994, vol. 1189, pp. 195-203
	Zhou et al., "Lipophilic polylysines mediate efficient DNA transfection in mammalian cells," <i>Biochimica et Biophysics Acta</i> ; 1991, vol. 1065, pp. 8-14
	Seetharam et al., "Increased cytotoxic activity of pseudomonas exotoxin and two chimeric toxins ending in kdel," <i>The Journal of Biological Chemistry</i> ; Sept. 15 1991, vol. 266, no. 26, pp. 17376-17381
	Senior et al., "Interaction of positively-charged liposomes with blood: implications for their application in vivo," <i>Biochimica et Biophysica Acta</i> ; 1991, vol. 1070, pp. 173-179
	Pastan et al., "Pseudomonas exotoxin: chimeric toxins" <i>The Journal of Biological Chemistry</i> ; Sept. 15 1989, vol. 264, no. 26, pp. 15157-15160
	Perez et al., "Comonomer sequence assignment of the Cn.m.r. spectra of some poly(epichlorohydrin) derivatives obtained by nucleophilic substitution," <i>Polymer</i> ; 1998, vol. 39, no. 17, pp. 3885-3892
	Nishikubo et al., "Degradation of dehydrochlorinated ly(epichlorohydrin) using photo-generated cationic catalysts," <i>Polymer Science: Part A: Polymer Chemistry</i> ; 1986, vol. 24, pp. 1097-1108
	Mechtler et al., "Gene transfer mediated by influenza virus peptides: the role of peptide sequences," <i>New Journal of Chemistry</i> ; 1997, vol. 21, pp. 105-111
	Kishore et al., "Polymers containing disulfide, tetrasulfide, diselenide and ditelluride linkages in the main chain," <i>Advances in Polymer Sciences</i> ; 1995, vol. 121
	Kichler et al., "Efficient gene delivery with neutral complexes of lipospermine and thiol-reactive phospholipids," <i>Biochemical and Biophysical Research Communications</i> ; 1995, vol. 209, no. 2, pp. 444-450



	Wolff et al., "Direct gene transfer into mouse muscle in vivo," Science; 1990, vol. 247, pp. 1465-1468
	Wolfert et al., "Characterization of vectors for gene therapy formed by self-assembly of DNA with synthetic block co-polymers," Human Gene Therapy; Nov. 1996, vol. 7, pp. 2123-2133
	Wagner et al., "Delivery of drugs, proteins and genes into cells using transferring as a ligand for receptor-mediated endocytosis," Advanced Drug Delivery Reviews; 1994, vol. 14, pp. 113-135
	Wagner et al., "Influenza virus hemagglutinin ha-2 n-terminal fusogenic peptides augment gene transfer by transferring-polylysine-DNA complexes: toward a synthetic virus-like gene-transfer vehicle," Proc. Natl. Acad. Sci.; Sept. 1992, vol. 89, pp. 7934-7938
	Wetering et al., "Copolymers of 2-(dimethylamino)ethyl methacrylate with ethoxyriethylene glycol methacrylate or n-vinyl-pyrrolidone as gene transfer agents," Journal of Controlled Release; 2000, vol. 64, pp. 193-203
	Trubetskoy et al., "Self-assembly of DNA-polymer complexes using template polymerization," Nucleic Acids Research; 1998, vol. 26, no. 18, pp. 4178-4185
	Trubetskoy et al., "Quantitative Assessment of DNA Condensation," Analytical Biochemistry; 1999, vol. 267, pp.1-5
	Trubetskoy et al., "Layer-by-layer deposition of oppositely charged polyelectrolytes on the surface of condensed DNA particles," Nucleic Acids Research; 1999, vol. 27, no. 15, pp. 3090-3095
	Trubetskoy et al., "Caged DNA does not aggregate in high ionic strength solutions," Bioconjugate Chem.; 1999, vol. 10, pp. 624-628
	Seymour et al., "Polymer Chemistry" polymer chemistry;
	Remy et al., "Gene Transfer with a series of lipophilic DNA-binding molecules," Bioconjugate Chem.; 1994, vol. 5, pp. 647-654
	Remy et al., "Targeted gene transfer into hepatoma cells with lipopolyamine-condensed DNA particles presenting galactose ligands: a stage toward artificial viruses," Proc. Natl. Acad. Sci.; Feb. 1995, vol. 92, pp. 1744-1748
	O'Brien-Simpson et al., "Polymerization of Unprotected Synthetic Peptides: A View toward Synthetic Peptide Vaccines," J. Am. Chem. Soc.; 1997, vol. 119, pp. 1183-1188
	Murthy et al., "the design and synthesis of polymers for eukaryotic membrane disruption," Journal of Controlled Release; 1999, vol. 61, pp. 137-143
	Meyer et al., "Copolymers of N-isopropylacrylamide can trigger pH sensitivity to stable liposomes," FEBS Letters; 1998, vol. 421, pp. 61-64
	Kresge et al., "vinyl ether hydrolysis. 9. isotope effects on proton transfer from the hydronium ion," Journal of the American Chemical Society; Oct. 1977, vol. 99, no. 22, pp. 7228-7233
	Kamata et al., "Amphiphilic peptides enhance the efficiency of liposome-mediated DNA transfection," Nucleic Acids Research; 1994, vol. 22, no. 3, pp. 536-537
	Goula et al., "size, diffusibility and transfection performance of linear PEI/DNA complexes in the mouse central nervous system," Gene Therapy; 1998, vol. 5, pp. 712-717
	Danko et al., "high expression of naked plasmid DNA in muscles of young rodents," Human Molecular Genetics; 1997, vol. 6, no. 9, pp. 1435-1443

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